

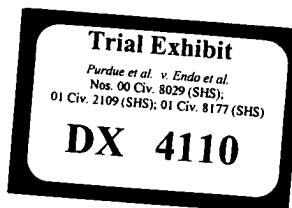
**TIME SENSITIVE PATENT INFORMATION PURSUANT TO
21 C.F.R. 314.53 (c) FOR NDA # 20-553**

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

Trade Name:	OxyContin®
Active Ingredient(s):	Oxycodone Hydrochloride
Strength(s):	10, 20, 40, 80 and 160 mg
Dosage Form:	Extended-Release Tablets
Approval Date:	10 mg. - December 12, 1995 20 mg. - December 12, 1995 40 mg. - December 12, 1995 80 mg. - January 6, 1997 160 mg. - March 15, 2000
Applicant:	Purdue Pharma L.P. One Stamford Forum Stamford, CT 06901-3431
Listed Drug:	OxyContin® (Oxycodone Hydrochloride) Controlled-Release Tablets
Indication(s):	OxyContin® (Oxycodone Hydrochloride) Controlled-Release Tablets are indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Confidential Information
Purdue v. Endo

P 650650



1. United States Patent No. 4,861,598

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 4,861,598Expiration Date: August 29, 2006

Type of Patent (indicate all that apply):

Drug Substance (Active Ingredient)	<u> </u> Y	<u> X </u> N
Drug Product (Composition/Formulation)	<u> X </u> Y	<u> </u> N
Method of Use	<u> </u> Y	<u> X </u> N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A

Name of Patent Owner: Euro-Celtique S.A.

U.S. Agent (if patent owner or applicant does not reside or have place of business in the U.S.):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 4,861,598 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

 X currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

 the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650651

2. United States Patent No. 4,970,075

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 4,970,075Expiration Date: August 29, 2006

Type of Patent (indicate all that apply):

Drug Substance (Active Ingredient)	<u> </u>	Y	<u> x </u>	N
Drug Product (Composition/Formulation)	<u> x </u>	Y	<u> </u>	N
Method of Use	<u> </u>	Y	<u> x </u>	N

- a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A.

Name of Patent Owner: Euro-Celtique S.A.

U.S. Agent (if patent owner or applicant does not reside or have place of business in the U.S.):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

- B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 4,970,075 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

 x currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

 the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650652

3. United States Patent No. 5,266,331

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,266,331Expiration Date: October 26, 2007Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)	<u> </u>	Y	<u> X </u>	N
Drug Product (Composition/Formulation)	<u> X </u>	Y	<u> </u>	N
Method of Use	<u> </u>	Y	<u> X </u>	N

- a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A

Name of Patent Owner: Purdue Pharma L.P.
The Purdue Frederick Company
The P.F. Laboratories, Inc.
The Purdue Pharma Company

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

- B The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,266,331 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

 X currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

 the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650653

4. United States Patent No. 5,508,042

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,508,042

Expiration Date: April 16, 2013

Type of Patent (indicate all that apply):

Drug Substance (Active Ingredient)	<input type="checkbox"/> Y	<input checked="" type="checkbox"/> N
Drug Product (Composition/Formulation)	<input type="checkbox"/> Y	<input checked="" type="checkbox"/> N
Method of Use	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N

- a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Name of Patent Owner: Purdue Pharma L.P.
 The Purdue Frederick Company
 The P.F. Laboratories, Inc.
 The Purdue Pharma Company

U.S. Agent (if patent owner or applicant does not reside or have place of business in the U.S.):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

- B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,508,042 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

☒ currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

☐ the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650654

5. **United States Patent No. 5,549,912**

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,549,912Expiration Date: October 26, 2007Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)	<u> </u> Y	<u> x </u> N
Drug Product (Composition/Formulation)	<u> x </u> Y	<u> </u> N
Method of Use	<u> </u> Y	<u> x </u> N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A.

Name of Patent Owner: Purdue Pharma L.P.
The Purdue Frederick Company
The P.F. Laboratories, Inc.
The Purdue Pharma Company

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,549,912 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

 x currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

 the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650655

6. United States Patent No. 5,656,295

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,656,295Expiration Date: October 26, 2007

Type of Patent (indicate all that apply):

Drug Substance (Active Ingredient)	<u> </u>	Y	<u> X </u>	N
Drug Product (Composition/Formulation)	<u> X </u>	Y	<u> </u>	N
Method of Use	<u> X </u>	Y	<u> </u>	N

- a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Name of Patent Owner: Purdue Pharma L.P.
The Purdue Frederick Company
The P.F. Laboratories, Inc.
The Purdue Pharma Company

U.S. Agent (if patent owner or applicant does not reside or have place of business in the U.S.):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

- B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,656,295 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

 X currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

 the subject of this application for which approval is being sought.

Signed:

Philip C. StrassburgerPhilip C. Strassburger
U.S. Patent and Trademark Office Registration No. 34,258Date: March 28, 2002

Title: Vice President, Intellectual Property Counsel
Purdue Pharma L.P.

Telephone Number: (203) 588-7639

Confidential Information
Purdue v. Endo

P 650656